Ofatumumab (Kesimpta)
Criteria for Use
September 2022

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the PBM Formulary Management - Home (sharepoint.com) for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive ofatumumab.

- ☐ Diagnosis of PPMS or SPMS without activity
- ☐ Untreated active Hepatitis B infection
- ☐ Pregnant or lactating women
- ☐ Untreated, active systemic infections
- ☐ Untreated latent or active tuberculosis infection
- ☐ Patient has untreated active Hepatitis B or not been screened for Hepatitis B

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care is provided by a VA/VA Community Care neurologist or designated MS expert (Spinal Cord Injury (SCI), PMR)
- ☐ A definitive diagnosis of a **relapsing form of multiple sclerosis [RMS]**(relapsing-remitting or secondary progressive multiple sclerosis with relapses, new and/ or enhancing lesions on MRI or with a subacute clinical deterioration) has been established

One of the following must be met

- ☐ Current treatment with natalizumab and patient has elevated risk factors for PML (anti JC virus antibody positive, duration of therapy > 24 months or received immunosuppressant therapy prior to natalizumab)
- ☐ Ineffectiveness, defined as meeting at least one of the following criteria during treatment with other MS DMT
    - The patient continues to have clinical relapses (at least one relapse within the past 12 months).
    - The patient continues to have CNS lesion progression as measured by MRI.
    - The patient continues to have worsening disability. Examples of worsening disability include, but are not limited to, decreased mobility, decreased ability to perform activities of daily living due to disease progression, or an increase in EDSS score.
- ☐ Highly aggressive disease as demonstrated by heavy burden of MRI T2 lesions, presence of multiple enhancing lesions at onset of disease, high burden of gadolinium enhancing lesions or rapid accrual of disability

- ☐ Patient unable to access an infusion center for administration of ocrelizumab or natalizumab
- ☐ Patient requires a shorter acting high efficacy DMT other than ocrelizumab due to infection risk and has contraindications to natalizumab.

Additional Inclusion Criteria

All of the following criteria must be met.

- ☐ For patients who are negative for HBsAg and positive for Hepatitis B core antibody (HBcAb+) or are carriers of HBV (HBsAg+), consult liver disease experts before starting and during treatment with ofatumumab.
- ☐ Perform testing for quantitative serum immunoglobulins. For patients with low serum immunoglobulins, consult immunology experts before starting treatment.
- ☐ Administer all immunizations per immunization guidelines at least 4 weeks prior to the start of treatment for live or live-attenuated vaccines and whenever possible, at least 2 weeks prior to the start of treatment for inactivated vaccines.

Other Justification

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